

**REMARKS**

Claim 1 has been amended to incorporate recitations of claim 2, and claim 2 has been canceled accordingly. Claim 1 has also been amended to resolve issues raised by the Examiner under 35 U.S.C. 112, including amendments based on the disclosure at, e.g., pages 13-14 in the specification, and to further distinguish over the cited art. The claims have also been amended to resolve an objection raised by the Examiner. Claims 16 and 17 have been added based on the disclosure at, e.g., pages 8-9 in the specification.

Entry of the above amendment is respectfully requested.

**Information Disclosure Statement**

Applicant submits herewith an Information Disclosure Statement. The Examiner is respectfully requested to consider the disclosed information and return an initialed PTO/SB/08 form with the next communication from the PTO.

**Election of Species**

On page 2 of the Office Action, in paragraph 1, the Examiner acknowledges Applicant's election of the species 13,14-dihydro-15-keto-16,16-difluoro-PGE<sub>1</sub>, and the Examiner indicates in paragraph 3 that claim 10 is withdrawn from consideration because it does not read on the elected species.

In response, Applicant submits that Claim 10 should be included among the elected claims. The compound recited in Claim 10 does not have any definition of Z at the 15-position and, therefore, includes both 15-keto and 15-hydroxy type compounds. Accordingly, Applicant

has not listed Claim 10 as a withdrawn claim, and examination of Claim 10 is respectfully requested.

### **Objection**

On page 2 of the Office Action, in paragraph 5, the Examiner has objected to claims 3-9 because, according to the Examiner, the phrase "wherein said prostaglandin compound is 16-mono..." (Claim 3) and "wherein said prostaglandin compound is 13,14-dihydro..." (Claims 4-9), should be changed to "wherein said prostaglandin compound is a 16-mono..." and "wherein said prostaglandin compound is a 13,14-dihydro...", respectively (emphasis added by the Examiner).

In response, Applicant has amended the claims to resolve this issue, and withdrawal of the objection is respectfully requested.

### **Rejection under 35 U.S.C. 112, Second Paragraph**

On page 3 of the Office Action, in paragraph 7, claims 2-9 and 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite.

#### **The Examiner's Position**

Based on the reasons given by the Examiner, the Examiner's position is as follows:

(1) Regarding Claim 2, the phrase "general formula" (emphasis added by the Examiner) renders the claim indefinite because the word "general" offers no probative value to the formula.

(2) Claim 2 is drawn to the "method of Claim 1, wherein said prostaglandin compound is the compound as shown" in formula (I), wherein "A is -CH<sub>3</sub>, or -CH<sub>2</sub>OH, -COCH<sub>2</sub>OH, -COOH or a functional derivative thereof" (emphasis added by the Examiner), but

the boundaries of the term "functional derivative" are not clearly defined in the specification or claims.

### **Applicant's Response**

Applicant's comments on each of the issues raised by the Examiner are set forth below:

- (1) With respect to the phrase "general formula", Applicant has deleted the word "general" from this phrase to resolve this issue.
- (2) As to the phrase "functional derivative", Applicant has amended "a functional derivative thereof" to "a salt, ether, ester or amide thereof" based on the disclosure at, e.g., page 14, lines 11-13 in the specification to resolve this issue.

Thus, Applicant submits that the present claims satisfy the requirements of 35 U.S.C. 112, second paragraph, and withdrawal of this rejection is respectfully requested.

### **Rejection under 35 U.S.C. 112, First Paragraph**

On page 4 of the Office Action, in paragraph 9, claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

### **The Examiner's Position**

The Examiner's position is that Claim 2 is drawn to the method of Claim 1, wherein said prostaglandin compound is the compound as shown in formula (I), wherein R<sub>1</sub> is a saturated or unsaturated bivalent lower or medium aliphatic hydrocarbon residue, which is unsubstituted or substituted with halogen, alkyl, hydroxy, oxo, **aryl or heterocyclic** group (emphasis added by the Examiner), but the Examiner indicates that there is insufficient written basis for R<sub>1</sub> being an undefined aryl or heterocyclic group in the specification.

### **Applicant's Response**

In response, Applicant notes initially that the Examiner has misinterpreted the recitation of R<sub>1</sub>. In particular, the Examiner raises an issue about embodiments in which R<sub>1</sub> is an aryl or heterocyclic group, but R<sub>1</sub> is an aliphatic hydrocarbon residue which can be substituted with an aryl or heterocyclic group, and is not itself an aryl or heterocyclic group.

Further, Applicant notes that the specification gives examples of aryl groups at page 13, lines 7-9 and examples of heterocyclic groups in the paragraph bridging pages 13-14 in the specification. Applicant submits that it is not necessary that Applicant give a working example of each embodiment contemplated for the invention, and that the written description set forth in the present specification should be sufficient.

However, to resolve this issue and expedite allowance, Applicant has amended the R<sub>1</sub> recitation to include the examples of aryl groups at page 13, lines 7-9 and the examples of heterocyclic groups in the paragraph bridging pages 13-14 in the specification.

Thus, Applicant submits that the present claims satisfy the requirements of 35 U.S.C. 112, first paragraph, and withdrawal of this rejection is respectfully requested.

### **Anticipation Rejections**

On page 6 of the Office Action, in paragraph 11, claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Evans et al. (U.S. Patent No. 6,830,882). Also, on page 6 of the Office Action, in paragraph 12, claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Pike et al. (U.S. Patent No. 3,888,919).

In response, Applicant has amended the claim 1 by introducing the formula recited in Claim 2 and further introducing the recitation "provided that Z is C=O and/or Ra is a saturated or

unsaturated lower or medium aliphatic hydrocarbon residue which has a halogen substituent".

Applicant submits that the compound of the formula (I) wherein Z is C=O and/or Ra has a halogen substituent is not disclosed in any of the cited prior art references.

Thus, Applicant submits that the present invention is patentable over the cited references, and withdrawal of these rejections is respectfully requested.

### **Related Co-Pending Applications and Patents**

On page 7 of the Office Action, in paragraph 13, the Examiner requests that the Applicant provides a listing of all related co-pending applications and patents.

In response, Applicant submits the following list of patents/applications which may be related to the instant application.

U.S. Application Nos.: 10/383581, 11/142,251, 10/298,062, 10/293,516, 11/190,842, 10/562,637, 10/745,689, 11/401,382, 11/216,012, and 11/384,491.

U.S. Patent Nos.: 5,284,858, 5,317,032, 6,583,174, 6,414,016, 6,982,283, 6,956,056, and 7,064,148.

Also, Applicant submits herewith an Information Disclosure Statement including these patents and the publications of these applications, as well as the Polis reference which was not sent to the PTO by the International Bureau. Applicant respectfully requests that the Examiner consider the disclosed information and return an initialed PTO/SB/08 form with the next communication from the PTO.

**Conclusion**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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